

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC.,
PELVIC REPAIR SYSTEM
PRODUCTS LIABILITY LITIGATION

MDL NO. 2327

THIS DOCUMENT RELATES TO ALL
WAVE 3 CASES¹

**PLAINTIFFS' REPLY IN SUPPORT OF MOTION AND MEMORANDUM TO LIMIT
THE OPINIONS AND TESTIMONY OF HARRY JOHNSON, JR., M.D.**

Plaintiffs hereby submit *Reply in Support of Motion and Memorandum to Limit the Opinions and Testimony of Harry Johnson, Jr., M.D.* and respectfully show the Court as follows:

I. INTRODUCTION

Defendants' Response to Plaintiffs' Motion is nearly identical to the Response filed in the *Mullins Consolidated Cases*. As such, Plaintiffs' Reply is also nearly identical to their Reply filed in the *Mullins Consolidated Cases*. For the convenience of the Court, any subsequent language in this Reply that is different than the language in Plaintiffs' prior reply is noted as follows: deleted text is ~~stricken through~~; additional text is underlined.

Defendants' Response mischaracterizes Plaintiffs' arguments with regard to Dr. Johnson's proffered testimony as related to a *Daubert* analysis: "Plaintiffs challenge neither Dr.

¹ In Defendants' Response [Dkt. 3295], they note: "Although Plaintiffs' Motion indicated that its Exhibit A contained a list of cases to which the motion would apply, as required by the Court's prior orders, no such exhibit was attached." Defs.' Resp. at 1 n.1. To the best of the undersigned's knowledge, Defendants have only designated Dr. Johnson as a general expert in *Kathy Blake v. Ethicon, Inc., et al.*, 2:12-cv-02943. If Plaintiffs are incorrect in this assertion, they welcome any clarification Defendants can provide. In any event, Plaintiffs' Motion applies to all Wave 3 cases in which Defendants have designated Dr. Johnson as a general expert.

Johnson's qualifications nor his methodology in relation to the vast majority of his proffered opinions. Plaintiffs' silence in this regard is a testament to Dr. Johnson's credentials and the reliability of his methodology." Defs.' Resp. at 1. The fact is Plaintiffs do challenge Dr. Johnson's qualifications, with regard to certain opinions, and his methodology with regard to others. That Plaintiffs have chosen to be selective in choosing and making their *Daubert* arguments is a testament to Plaintiffs' desire to not utilize a "scattershot" approach to exclusion, but rather, present meritorious arguments. For the reasons outlined in Plaintiffs' Motion, and described in more detail herein, Plaintiffs respectfully request the Court grant their Motion in its entirety.²

II. ARGUMENT

Defendants incorporate the standard of review for *Daubert* challenges as set forth in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 701 (S.D. W. Va 2014), Defs.' Resp. at 2, while Plaintiffs lay out a standard of review that is virtually identical in substance. *See* Pls.' Mot. at 2-4. As such, either standard of review is applicable to Plaintiffs' instant Motion.

A. **Dr. Johnson's TVT-O Opinions Are Irrelevant And Should Be Excluded.**

Dr. Johnson's TVT-O opinions are not relevant to a consolidated group of cases in which all plaintiffs were implanted with TVT. Both Dr. Johnson and Defendants' attorney defending Dr. Johnson in deposition are aware of this fact. Pls.' Mot. at 4-5. Contrary to Defendants' assertion, Plaintiffs are not making a "simplistic argument", Defs.' Resp. at 10, but rather, Plaintiffs are making a common sense argument that is mostly self-evident. By Defendants' logic, *i.e.*, both the TVT and TVT-O utilize Prolene, and therefore, Dr. Johnson's opinions on

² Defendants correctly note that Plaintiffs inadvertently attached an incorrect deposition transcript of Dr. Johnson as Ex. ~~D C~~ to their Motion. Defs.' Resp. at ~~6, n.1~~ at 9, n.4. As such, a revised **Exhibit D C** is attached hereto.

TVT-O are relevant, then Dr. Johnson should be allowed to opine on nearly all of Defendants' pelvic floor products. Only relevant evidence is admissible, Fed. R. Evid. 402, and even assuming for the sake of argument that Dr. Johnson's TVT-O opinions are remotely relevant, those opinions would offend Federal Rule of Evidence 403 as confusing, misleading, and wasting the time of the parties and the Court when presented. As such, Dr. Johnson's TVT-O opinions should be excluded.

Defendants' primary argument that Dr. Johnson's TVT-O opinions are relevant in Wave 3 is that: "Wave 3 plaintiff, Christina Webb, was implanted with Defendants' TVT-O product and complains of related injuries . . . Plaintiffs' motion should be denied on this ground alone." Defs.' Resp. at 13. However, as noted above, Plaintiffs are aware of Dr. Johnson's designation as a general expert in only one Wave 3 case: *Kathy Blake v. Ethicon, Inc., et al.*, 2:12-cv-02943, and as such, Dr. Johnson's general opinions on TVT-O remain irrelevant in Wave 3.

B. Dr. Johnson's Uncited Opinions Should Be Excluded, Or At The Court's Discretion, His Expert Report Should Be Excluded In Its Entirety.

Defendants' pay relatively short shrift to Plaintiffs' arguments with regard to Dr. Johnson's failure to provide a proper reliance list as required by Federal Rule of Civil Procedure 26 and for failing to cite many of his opinions in his expert report by conclusorily stating: "Dr. Johnson's Report satisfies both the spirit and the letter of Rule 26." Defs.' Resp. at 16. Dr. Johnson's expert report does neither, and Defendants make no argument as to how the failure to provide a proper reliance list was substantially justified or harmless, and therefore, all uncited opinions in Dr. Johnson's expert report should be excluded, or his opinions should be excluded in their entirety.

Defendants initially argue that Plaintiffs only point to one of Dr. Johnson's opinions that lacks a citation, implying that Plaintiffs do not "take issue," Defs.' Resp. at 15, with other

uncited opinions. This is not the case. Plaintiffs cited an *example* of one of Dr. Johnson's uncited opinions in their Motion, and specifically argued: "Dr. Johnson offers a number of uncited opinions and conclusions." Pls.' Mot. at 5. The fact is that Dr. Johnson failed to disclose an expert report in conformity with Federal Rule of Civil Procedure 26 and Plaintiffs offered a practical and simple way to remedy this noncompliance: exclude all uncited opinions in his expert report. Of course, as noted in Plaintiffs' Motion, it would also be well within the Court's discretion to entirely exclude Dr. Johnson's opinions.

Second, Defendants argue "even a cursory review of Dr. Johnson's Report reveals that all substantive discussions regarding the safety and efficacy of TVT . . . provide citations to the authorities upon which those opinions are based." Defs. Resp. at 15. Defendants then fail to cite to a single portion of Dr. Johnson's expert report where this is true. In contrast, Plaintiffs' example of an uncited opinion contained in Dr. Johnson's expert report contains specific statistical-based opinions, which Defendants argue come from Dr. Johnson's "decades-long experience." Defs. Resp. at 16. However, it is unclear how Dr. Johnson analyzed his "decades-long experience" to specifically opine: "Up to 50% of women may improve enough to forego surgical treatment initially, however >90% of these patients remain incontinent and > 60 % [sic] may subsequently seek surgical management." Pls.' Mot. at 5. Unless Dr. Johnson's "decades-long experience" encompasses *all* women in *all* places that undergo treatment for stress urinary incontinence, Dr. Johnson must have drawn upon some source for this opinion. As expressed in Plaintiffs' Motion, because Dr. Johnson's reliance list ~~and supplemental reliance list~~ provided Plaintiffs with a metaphorical "haystack," this opinion, and all other uncited opinions should be excluded. Plaintiffs have no way to determine the basis for such opinions, and therefore, are

prevented from Defendants' inexcusable neglect from properly preparing to rebut Dr. Johnson's testimony at trial.

Finally, Defendants argue that Plaintiffs could have asked for the basis of all of Dr. Johnson's opinions at deposition. Putting aside time constraints that make this a practical impossibility, Defendants provide no basis for how this hypothetical possibility excuses their failure to provide an expert report that conforms with Federal Rule of Civil Procedure 26. As this argument does not excuse Defendants' failure to conform with the Federal Rules, Dr. Johnson's uncited opinions should be excluded, or at the discretion of the Court, all of his opinions should be excluded.

C. Dr. Johnson Should Not Be Permitted To Opine That Defendants' TVT Is The "Gold Standard."

Defendants argue that when Dr. Johnson's deposition testimony is not "trucat[ed]," the basis for his "gold standard" opinion is apparent. Defs. Resp. at 5. However, this argument is unavailing as Defendants' cited deposition testimony further demonstrates the basis for Plaintiffs' argument in that Dr. Johnson testified "they were *relatively equivalent* [in reference to TVT and TVT-O]" and reiterates that using the TVT is the "most commonly performed procedure for stress incontinence in the world." Defs. Resp. at 6 (emphasis added). Thus, Dr. Johnson's opinion with regard to TVT being the "gold standard" remains unduly prejudicial and unsupported by any scientific basis, and therefore, should be excluded.

Moreover, to the extent that Dr. Johnson's "gold standard" opinion is based on a comparison to TVT-O, this opinion is all the more improper given that Dr. Johnson's TVT-O opinions should be excluded in their entirety.

D. Defendants' Agree That Dr. Johnson Will Not Opine On The FDA Section 510(K) Process, And Therefore, Plaintiffs' Argument Is Moot.

While Defendants “respectfully re-submit[] that the 510(k) process is relevant and evidence of TVT’s 510(k) clearance,” Defs.’ Resp. at 3, Defendants also unequivocally state: “Dr. Johnson does not intend to opine on the FDA 510(k) clearance process.” Id. As such, with this assurance from Defendants, Plaintiffs’ argument in this regard is moot.

E. Dr. Johnson Should Not Be Permitted To Testify On The Adequacy Of Defendants’ IFU.

Defendants misunderstand Plaintiffs’ arguments in this regard. Plaintiffs make three arguments: (1) Dr. Johnson should not be permitted to opine that Defendants’ IFU was adequate when he testified to the contrary; (2) he is unqualified to testify to adequacy; and (3) Dr. Johnson, by his own acknowledgment, admits that the 2015 TVT IFU change is irrelevant. First, Defendants do not rebut that Dr. Johnson’s testimony was contrary to the opinions expressed in his expert report. With regard to the second argument, Defendants’ own cited authority is supportive of Plaintiffs’ position. In *Hovey v. Cook, Inc.*, plaintiffs’ expert was, by assurance of plaintiffs, not going to testify regarding defendants’ IFU in a “regulatory context.” Defs.’ Resp. at 4. Here, when Dr. Johnson seeks to testify that Defendants’ IFU is *adequate*, he is necessarily proffering an opinion that requires knowledge of the regulatory process. Dr. Johnson does not possess this knowledge nor do Defendants direct the Court to any of Dr. Johnson’s qualifications that demonstrate an expertise with FDA regulations. As such, he is unable to opine on whether Defendants’ IFU was in fact adequate and his opinions on Defendants’ IFU should be excluded.

Moreover, Defendants’ arguments with regard to the contours of a device manufacturer’s duty to warn are misplaced in a *Daubert* analysis. *See* Defs. Resp. at 7-9. A *Daubert* analysis focuses on reliability and relevance. Defendants’ arguments related to a manufacturer’s duty to warn could possibly inform the Court on the relevance prong, except that not a single cited authority is a statement of West Virginia law. Id. (citing among other inapposite cases, a case in

which a federal district court predicted that West Virginia law would adopt the “sophisticated user defense” as described in the Restatement (Second) of Torts). While Defendants assert “Plaintiffs’ argument about the reliability of Dr. Johnson’s IFU testimony is that they contend Ethicon could have exceeded this standard [referring to Defendants’ duty to warn],” Defs. Resp. at 9, this is not Plaintiffs’ argument. Plaintiffs’ argument is exactly as stated in their Motion: Dr. Johnson is not qualified to proffer these opinions. Defendants’ argument in this regard undercuts the significance of their “duty to warn” argument as related to relevance in that Defendants’ opinion that Plaintiffs are actually arguing that “Ethicon could have exceeded this standard” implies that Dr. Johnson understands this “standard” (if his testimony is to be relevant), when he possesses no credentials to testify as to adequacy of Defendants’ IFU.

Finally, Defendants argue Dr. Johnson’s opinions related to the 2015 IFU change are relevant in spite of Dr. Johnson’s admissions that they are not. Defs. Resp. at 12-13. Defendants concede in their Response: “The fact that the risks were added to the IFU in 2015 is not relevant to this consolidated action.” *Id.* at 13. As such, Dr. Johnsons’ opinions on the 2015 IFU changes should be excluded. Defendants go on to argue that Dr. Johnson’s opinion that the specific risks added to the 2015 IFU are “general surgical risks of all pelvic floor surgeries,” and therefore, his opinion becomes relevant because it “go[es] to the heart of Plaintiffs’ failure to warn claims,” *Id.*, is illogical. Dr. Johnson intends to testify as to what general risks are entailed in pelvic floor surgeries, but Defendants offer no explanation as to why this must be done in the context of the 2015 IFU change. These changes were effected long after Plaintiffs were implanted with TVT, and as such, are irrelevant. Additionally, any opinions proffered by Dr. Johnson regarding

Defendants' TVT-O IFU, or changes thereto, are also irrelevant on separate grounds described herein.³

F. Dr. Johnson's opinions based on the SISTER and E-SISTER trials should be excluded.

Defendants' arguments in support of the admissibility of Dr. Johnson's opinions based on the SISTER and E-SISTER trials can be boiled down to: "Plaintiffs merely speculate that the jury will make this analytical leap [referring to Plaintiffs' argument that Dr. Johnson's opinions, apart from being irrelevant, possess the real possibility of confusing the jury]." Defs.' Resp. at 12. Defendants further argue: "If the TVT surgery is safer than the alternative non-mesh surgeries, then it would be fair for the jury to infer that the product is safe." Id. Defendants' argument perfectly illustrates the problem posed by Dr. Johnson's testimony. The fact that non-mesh surgeries may or may not have high incidents of adverse events does not lead to a fair inference that Defendants' products are safe. Rather, this type of inference likely results from confusion, and therefore, Dr. Johnson's opinions in this regard should be excluded.

G. Dr. Johnson's Opinions That Rely Upon The Ford Cochrane Review 2015 Should Be Excluded.

Defendants argue: "Dr. Johnson's opinion should not be excluded just because Plaintiffs disagree with the quality of the evidence upon which he relies." Defs.' Resp. at 15. Defendants misunderstand Plaintiffs' arguments, which attack the reliability and relevance of Dr. Johnson's

³ Plaintiffs also note that Defendants argue Plaintiffs' position in this regard is inconsistent with their opposition to a motion *in limine* filed by Defendants. Defs.' Resp. at 13. However, this is not the case as evidence may be excluded or admitted on different bases and for different purposes, and here, Plaintiffs are arguing that Dr. Johnson's opinions on the 2015 IFU changes are irrelevant and unsupported by his qualifications. That Plaintiffs may want to admit evidence of the 2015 IFU changes for a different purpose than that proposed by Defendants (through Dr. Johnson's testimony) does not render Plaintiffs' position inconsistent. Moreover, Defendants are guilty of their own accusation, *i.e.*, Defendants filed a motion *in limine* to exclude the 2015 IFU changes but desire that Dr. Johnson opine on this same evidence.

opinions based upon the Review. Pls.' Mot. at 12-14. Defendants completely fail to respond to these arguments, *see* Defs.' Resp. at 14-15, and as such, Dr. Johnson's opinions in this regard should be excluded.

III. CONCLUSION

For the reasons contained in Plaintiffs' Motion and those stated herein, Plaintiffs respectfully request the Court grant their Motion in its entirety.

Dated: January 3, 2017

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on January 3, 2017 a true and correct copy of **Plaintiffs' Reply In Support Of Motion And Memorandum To Limit The Opinions And Testimony Of Harry Johnson, Jr., M.D.** was served via electronic mail with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the CM/ECF counsel of record.

Dated: January 3, 2017

Respectfully submitted,

By: /s/ Aimee H. Wagstaff